REMARKS/ARGUMENTS

Status of the Claims

Claims 1-39 were pending in this application. Claims 1-18, 11-16, 19-27 and 29-39 are withdrawn from consideration in accordance with the Response to Restriction/Election Requirement dated January 3, 2007. Claims 9, 10, 17, 18 and 28 are herein cancelled. New Claims 40-43 are herein added. Hence, upon entry of the present amendments, only claims 40-43 will be pending and under active consideration.

No new matter has been added to the application. Applicants reserve the right to pursue unelected subject matter in divisional applications, and unclaimed subject matter within the elected invention in continuation applications.

Information Disclosure Statement

Applicants gratefully note the acknowledgement of the Information Disclosure Statements submitted on August 3, 2004 and June 8, 2005.

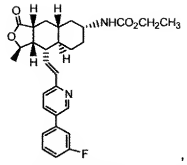
Specification

The Abstract was objected to on the grounds that it included legal phraseology, specifically the word "said," and that it comprised more than a single paragraph.

Applicants have herein amended the Abstract to substitute the word "the" for the word "said" and to combine the material from the two paragraphs into a single paragraph, thus overcoming the rejection.

New Claims

Unlike the previously pending claims, new Claims 40-43 are directed to methods of treating a single indication, acute coronary syndrome. Claim 40 claims such methods comprising orally administering a therapeutically effective amount of the thrombin receptor antagonist of the formula



or a pharmaceutically acceptable isomer, salt, solvate or co-crystal form thereof, in a solid pharmaceutical composition. Claim 41 is directed to such methods, wherein the thrombin receptor antagonist is the bisulfate salt of the compound whose structure is shown above. Claims 42 and 43 are dependent on Claim 40, further comprising the steps of administering aspirin and clopidogrel bisulfate, respectively. Thus, Claims 40-43 are limited to the single indication of acute coronary syndrome and to the single thrombin receptor antagonist whose structure is shown above, and the pharmaceutically acceptable isomers, salts, solvates or co-crystal forms thereof, in a solid pharmaceutical composition. Consequently, the scope encompassed by new claims 40-43 is considerably narrowed with respect to the scope encompassed by previously pending claims 9, 10, 17, 18 and 28.

Claim Rejections – 35 USC §112

Claims 9, 10, 17, 18 and 28 are rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly fails to reasonably provide enablement for treating a therapeutic condition. It is stated that "... one skilled in the art would be forced to perform an exhaustive search for the embodiments of any drugs having the function recited in the instant claim suitable to practice the claimed invention..." and further that "... a person of skill in the art would not be able to fully practice the instant invention without **undue experimentation**." (Office Action, p. 7, emphasis as in original).

This rejection is rendered moot by the cancellation of claims 9, 10, 17, 18 and 28. As discussed above, new claims 40-43 are limited to the treatment of only acute coronary syndrome ("ACS"), and that by oral administration of a single compound, or a pharmaceutically acceptable isomer, salt, solvate or co-crystal form thereof, in a solid pharmaceutical composition. Thus, with respect to the new claims at least, Applicants submit that one skilled in the art would not be forced to "perform an

exhaustive search" for embodiments of the drugs that have the function required to practice the claimed methods. Since the new claims are limited to the treatment of a single set of symptoms (ACS) by administration of a single compound or its pharmaceutically acceptable isomers, salts, solvates and co-crystal forms, it is not true that an exhaustive search would be necessary to practice the claimed invention. On this basis, Applicants respectfully submit that the newly added claims satisfy the requirements of 35 U.S.C. §112, first paragraph.

Claim Rejections – 35 USC §102

Claims 9 and 10 are rejected under 35 U.S.C. §102 over Chackalamannil *et al* (U.S. Pat. No. 6,063,847) as evidenced by Gerlitz *et al* (U.S. 2003/0022354). This rejection is rendered moot by the cancellation of claims 9 and 10.

As a preliminary matter, Applicants note that in the Office Action at p. 7, under the heading "Claim Rejections – 35 USC **§102**," it is stated that "Claims 9-10 are rejected under 35 U.S.C. **103(a)**... [emphasis added]. Upon bringing the apparent discrepancy in statutory bases for the rejection to the Examiner's attention in a brief telephone conference, the Examiner stated that the statutory basis is indeed 35 §102(b) rather than §103(a). The following response is grounded on that understanding.

As discussed above, new claims 40-43 are directed to methods of treating acute coronary syndrome by orally administering the single thrombin receptor antagonist shown in claim 40, or a pharmaceutically acceptable isomer, salt, solvate or co-crystal form thereof, in a solid pharmaceutical composition. This compound is not within the scope of compounds disclosed in U.S. Pat. No. 6,063,847 ("the '847 patent"). The '847 patent discloses a variety of tricyclic compounds. The right-hand ring (designated "Q" therein) and its substituents are defined as follows:

Q is

wherein n_1 and n_2 are independently 0-2; or when the double bond is not present, Q is also fused R-substituted aryl or R-substituted heteroaryl;

R is 1 to 3 substituents independently selected from the group consisting of H, C_1-C_6 alkyl, halogen, hydroxy, amino, (C_1-C_6)alkyl-amino, (C_1-C_6)dialkylamino, (C_1-C_6)alkoxy, -COR^{16}, -$COOR^{17}$, -SOR^{16}, -SO_2R^{16}, **-$NR^{16}COR^{16a}$, -$NR^{16}COOR^{16a}$, -$NR^{16}CONR^4R^5$**, fluoro-(C_1-C_6)alkyl, difluoro(C_1-C_6)alkyl, trifluoro(C_1-C_6)alkyl, C_3-C_6 cycloalkyl, C_2-C_6 alkenyl, aryl(C_1-C_6)alkyl, aryl(C_2-C_6)alkenyl, heteroaryl(C_1-C_6)-alkyl, heteroaryl(C_2-C_6)alkenyl, hydroxy(C_1-C_6)alkyl, amino(C_1-C_6)-alkyl, aryl and thio(C_1-C_6)alkyl;

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R^{16} and R^{16a} are independently selected from the group consisting of **C_1-C_6 lower alkyl, phenyl or benzyl**;

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USPN 6,063,847, pp. 2-4 (Emphasis added).

Thus, in the '847 patent, substituents on the right-hand ring that include an amine directly bonded to a ring member (as indicated within the definition of R as -$NR^{16}COR^{16a}$, -$NR^{16}COOR^{16a}$, -$NR^{16}CONR^4R^5$) are limited to derivatives of secondary amines (*i.e.*, where R^{16} is not hydrogen). Within this group, carbamates are limited to secondary amine carbamates, *i.e.*, -$NR^{16}COOR^{16a}$ where R^{16} is not hydrogen. This is true because H is not included in the definition of R^{16} and R^{16a}. The generic claim of the '847 patent does not disclose carbamates of primary amines (*i.e.*, -$NHCOOR^{16b}$).

In contrast, the substituent on the right hand ring in the compound of Claim 40, $NHCO_2CH_2CH_3$, renders the compound a carbamate of a primary amine, and thus not within the scope of the '847 patent. However, Applicants point out that, *the compound of Claim 40 is disclosed and claimed in co-pending application no. 10/412,982*, the corresponding PCT application no WO03/089428 having published on November 3, 2003.

Hence, Applicants respectfully submit that the §102(b) rejection would not apply to new claims 40-43 on the grounds that the cited reference does not disclose the sole compound whose structure is given in claim 40.

Claim Rejections – Obviousness Type Double Patenting

Claim 9 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of the '847 patent. As explained above, the '847 patent discloses a genus of compounds that does not encompass the compound of new claim 40.

Claim 9 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of the co-pending applications US 2006/0079684 and US 2006/0173189. Applicants point out that US 2006/0079684 discloses a genus of compounds in which the common member of the left hand- and center- rings is substituted, in contrast to the compound of new claim 40, in which that common ring member is unsubstituted. As stated in the Office action, US 2006/0173189 is directed to synthesizing the compound of Claim 40. Applicants would traverse an obviousness-type double patenting rejection of Claim 40, which is directed to a method of treating acute coronary syndrome, in view of a claim to the synthesis of the compound used in the method.

Claim 9 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 of the '847 patent and claim 9 of U.S. 6,326,380 ("the '380 patent"). Applicants have discussed the '847 patent above. The '380 patent is directed to a set of bicyclic compounds that are in distinction to the tricyclic compound of Claim 40.

Claim 9 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45 and 51 of US2005/0130975 and claim 1 of U.S. Ser. no. 11/613,450 in view of the '847 patent, as evidenced by Gerlitz *et al.* The inventor in US2005/0130975 is David L. Barbeau, and the claimed subject matter appears to be unrelated to the subject matter of the instant application. Thus, Applicant conjecture that US2005/0130975 is cited in error.

Claim 1 of U.S. Ser. no. 11/613,450 recites,

> A method of preventing a condition associated with coronary arterial bypass graft surgery comprising administering an effective amount of at least one thrombin receptor antagonist to a subject of said surgery.

Applicants would traverse a rejection of a method of treating acute coronary syndrome based on a pending claim to a method of preventing a condition associated with coronary arterial bypass graft surgery.

On the grounds of the foregoing, Applicants submit that the obviousness type double patenting rejections would not apply against new claims 40-43.

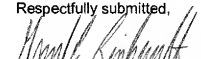
The Examiner is invited to contact the undersigned with any questions that may arise.

AUTHORIZATION

The Office action to which this paper is responsive was mailed on March 23, 2007 with a shortened statutory period for reply set to expire three months thereafter, on June 23, 2007. This Response is transmitted prior to expiration of the three-month extension of this date, and thus Applicants authorize the Commissioner to draw $1,020.00 from Applicants' deposit account no. 19-0365. Should any further such fee become necessary to render this Response timely filed, the Commissioner is authorized to draw the required amount from Applicants' deposit account no. 19-0365.

September 21, 2007

Respectfully submitted,



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